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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,478	11/20/2000	Emory V. Anderson	24727-813C	9900

24961 7590 05/22/2002

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EXAMINER

DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 05/22/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/717,478	ANDERSON ET AL.	
	Examiner	Art Unit	
	Deborah A Davis	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> | 6) <input type="checkbox"/> Other:  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 1 objected to because of the following informalities: "reflectence" is misspelled and should be "reflectance". Appropriate correction is required.
2. Claim 1 objected to because of the following informalities: "of to a" is incorrect grammar. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 1 recites the limitation "the surface" in line one. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the intensity" in 11. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 2, line 1, "the reader" lacks antecedent basis and is confusing and indefinite as to which reader it refers to.

Lines 1-2, " a reflectance reader" and "a reader head" are confusing and indefinite because it is unclear whether these two elements are the same ones as

recited in claim 1. Also, such a limitation is redundant since claim 1 already discloses "a reader head in a reflectance reader".

7. Claim 3 recites the limitation "the data" in line 4. There is insufficient antecedent basis for this limitation in the claim. The same problem exists in claim 6.

Line 3, recites "the software" lacks antecedent basis.

8. Claim 5, lines 1-2, "the reader is a reflectance reader" is confusing and indefinite because it is unclear as to which reader in claim 1 is the reflectance reader.

Line 3, "a reader head" is confusing and indefinite because it is not clear as to which reader "a reader head" refers to.

Line 10, "the light photodetector" lack antecedent basis.

9. Claim 6, line 1, "the reader" is confusing and indefinite because it is unclear as to which reader in claim 5 that it refers to.

Line 4, "the software" lack antecedent basis.

9. The term "substantially" in claim 11 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term substantially does not clearly indicate to what degree the wavelength reflects from the regions of the test strip. The same problem exists in claim 5.

Line 3, "the reading" lack antecedent basis.

10. The term "substantially optimally" in claim 12 is a relative term which renders the claim indefinite. The term "substantially optimally" is not defined by the claim, the

specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term substantially optimally does not clearly indicate to what degree the wavelength reflects from the region of the test strip.

The limitation "the surface comprises an assay test strip" is confusing, because an assay test strip should comprise the surface.

11. Claim 13 recites the limitation "wherein the analyte is fetal fibronectin" in line one. There is insufficient antecedent basis for this limitation in the claim.

12. Claim 14 recites the limitation "wherein the analyte is fetal fibronectin" in line one. There is insufficient antecedent basis for this limitation in the claim.

13. Claim 15, line 1, "a stripe" is vague and indefinite because its meaning is unclear.

### ***Drawings***

14. New formal drawings are required in this application because the preliminary amendment sent in by applicant that amended labeled components of the drawings are confusing. One example is that the test window labeled "308" that applicant mentioned in Figure 2B, but shown in Figure 3, is now amended to be "314", but label "308" has not been redefined. Also, in an alternative embodiment, Figure 3 of the drawings are not showing the test strip labeled "100". Please clearly label all components of drawings and redefine replacement labels. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the

Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

16. Claims 1, 3, 4, and 8-10 are rejected under 35 U.S.C. 102(a) as being anticipated by James Connolly (WO96/13707).

Connolly illustrates how to read the surface of a test strip with an optical reading apparatus. This apparatus contain a separate optical readhead that determines color and shade of a test strip while being inserted (pg. 3, lines 33-35). Connolly teaches a light detector or sensor is able to take a reading of light reflected from the surface of a test strip (pg. 17, lines 2-10). Connolly discloses the use of two wavelengths can allow one to define the pseudo endpoint algorithm, which can allow for an increased range of a chemistry reaction (pg. 21, para 3). In addition, Connolly discusses the use of multiple wavelengths to correct problems in positioning the strip in the apparatus (pg. 21, para 4). Connolly teaches an EEPROM unit that is connected to a microprocessor/microcontroller containing measurement parameters, software, calibration data and a means for recognizing a reagent on a test strip (pg. 17, 1<sup>st</sup> and 2<sup>nd</sup> para). The photometer includes a separate optical reader head (pg. 3, line 33) light

emitting diodes (LED) are contained in a housing to illuminate the test strip containing the sample (pg. 17, lines 1-5). An immunoassay can be performed on the test strip using immunological reagents that generate specific signals when exposed to a target analyte (pg. 3, lines 21-23). When the proper amount of a sample is applied to the strip, the apparatus goes through three measurement cycles, with the third measurement determining the final density. The density is compared to a table of values through the use of an algorithm stored in the EEPROM (pg. 19, 2<sup>nd</sup> para). Chromophore indicators are used along with multiple wavelengths to better enhance the range of chemistry on a test strip (pg. 21, 2<sup>nd</sup> para). Also the use of fluorescent labels is used for analyte detection (pg. 14, table VIII). Once the analyte is determined on a test strip, it produces color (pg. 19, lines 12-16).

***Claim Rejections - 35 USC § 103***

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 2, 5, 6, 7, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over James Connolly in view of Ralph S. Hernicz (USP 4,659,229).

See above teachings for James Connolly.

Connolly differs from the instant invention in failing to specifically disclose an aperture in a readhead and the use of fiberoptic bundles.

Hernicz teaches a readhead that contains an aperture (34) to allow light to transmit through (col. 4, lines 1-2). Hernicz also teaches the use of fiberoptic bundles (54 and 56) for illuminating a sample and measuring reflected light (Summary invention and Figure 3). Such a structure of optical head would provide a new and improved readhead for a spectrophotometer cable of more efficient measurements of multiple samples accurately, with reduced height sensitivity (Summary of the invention section).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to have provided in the readhead of Connolly an aperture and fiberoptic bundles as taught by Hernicz, in order to provide a new and improved read for a spectrophotometer capable of more efficient measurements of multiple samples accurately, with reduced height sensitivity. With respect to the wavelengths relative to regions of the test strips, as recited in claims 11 and 12, one of ordinary skill in the art would have found it obvious to illuminate a particular wavelength over a certain region of the test strip in order to optimize the measurement of the analyte on the test strip, depending on the structure of the test strip.

19. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over James Connolly in view of Senyei et al (WO92/10585).

The teachings of Connolly are set forth above.



Connolly fails to specifically teach the detection of fetal fibronectin; although he does acknowledge that a variety of analytes can be determined by using detection methods in his apparatus (pg. 10, 1<sup>st</sup> para).

Senyei et al teaches a method and assay for detecting fetal fibronectin in a sample (pg. 7, line 3) that indicates normal or eptopic pregnancy (pg. 5, lines 15-28 and pg. 7, lines 15-19). He also teaches that a pink or red spot (i.e. stripe) in the test zone as well as in the control zone of the strip indicates a positive detection of fetal fibronectin. Negative test results of fetal fibronectin, is indicated by a red color in the procedural control area of the test strip (pg. 59, lines 10-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method and assay of Connolly to measure fetal fibronectin as taught by Senyei in order to determine normal or eptopic pregnancy and use color as an indication of test results. Further, Connolly discloses that a variety of analytes can be used in his method.

20. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over James Connolly in view of Ralph Hernicz as applied to claim 5, and in further view of Senyei et al for the same reasons discussed in the rejection of claim 13 above.

### ***Conclusion***

21. *No claims are allowed.*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.



Deborah A. Davis  
CM1, 8D08  
May 17, 2002



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05/20/02